

**REMARKS**

Initially, Applicants thank the Examiner for withdrawing several of the rejections of record in the Office Action. Applicants note that new claim 8 is fully supported by the specification, specifically at pages 5-7. Applicants also note that the Examiner indicated in the Office Action that such a claim should be allowable.

Reconsideration and withdrawal of the rejections of record is respectfully requested.

***Summary of Status of Amendments and Office Action***

In the present amendment, claims 3-5 and 7 are amended, and claim 8 is added. Claims 1-2 and 6 have been previously canceled. Therefore, claims 3-5, 7 and 8 are pending in the application with claim 3 being independent.

Claims 3-5 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claims 4-6, and 7 are objected to under 37 C.F.R. 1.75(c) for allegedly being in improper dependent form.

Claims 3-5 and 7 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement.

***Response to §112, Second Paragraph Rejections***

Claims 3-5 and 7 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. The Office Action asserts that claims 3-5 and

7 contain subject matter which was not described in the specification in such a way as to reasonably convey to one in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action notes that the specification, at page 5, paragraph 4 defines “an apoptosis related protein which binds to NADE” to include something “which includes unknown” compounds. Therefore, the Office Action asserts that Applicants did not have possession of the claimed subject matter. The Office Action notes that if the claim was limited to the examples cited, the claims would be allowable.

In response, Applicants note that 35 U.S.C. § 112, first paragraph does not require that Applicants exemplify each limitation of a claim to comply with the written description requirement. The Examiner's attention is respectfully directed to longstanding case law such as In re Kaslow, 217 USPQ 1089 (Fed. Cir. 1983), in which the court, quoting the U.S. Patent and Trademark Office Board of Appeals, stated, at 1096:

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. (Emphasis added). In re Edwards, 558 F.2d 1349, 196 USPQ 465 (CCPA 1978); In re Herschler, 591 F.2d 693, 200 USPQ 711 (CCPA 1979).

Thus, the application must only reasonably convey to the skilled artisan that the inventor had possession of the claimed subject matter at the time of filing the application, and it is not necessary for the originally filed application to provide literal support.

Applicant further submits that the weight of authority supports Kaslow, as exemplified by, e.g., Staehlin v. Secher, 24 USPQ2d 1513 (BPAI 1992), in which the Board stated, at 1519:

The inquiry into satisfaction of the written description requirement is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. In re Wertheim, 646 F.2d 527, 191 USPQ 90 (CCPA 1976). Satisfaction of the 'written description' requirement does not require *in haec verba* antecedence in the originally filed application. In re Lukach, 440 F.2d 1263, 169 USPQ 795 (CCPA 1971).

Thus, satisfaction of the written description depends upon a factual inquiry into the nature of the invention and the amount of knowledge imparted by virtue of the originally filed application.

In the present case, Applicants have exceeded the standard set for in In re Kaslow. The originally filed application sets forth no less than 5 specific examples of apoptosis related proteins which binds to NADE. Thus, the application "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter" and the rejection should be withdrawn.

Finally, as noted in the Office Action, Applicants have given several examples of "apoptosis related protein which binds to NADE." Applicants are not required to set forth every possible protein which would satisfy this limitation to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. See e.g., Enzo Biochem., Inc. v. Gen-Probe, Inc., 296 F.2d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002); Fiers v. Revel, 984 F.2d 1164, 25

USPQ2d 1601 (Fed. Cir. 1993); Univ. Of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The Federal Circuit also has not found that a patent claim was invalid under the written description requirement simply because it covers material which is presently unknown. See, Amgen v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Finally, the Federal Circuit itself has stated that the written description requirement should not be more harshly applied for biotech inventions than for other classes of inventions which clearly allow for the coverage of currently unknown embodiments. Moba B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 66 USPQ2d 1429 (Fed. Cir. 2003).

In view of overwhelming weight of case law on the subject of written description requirement, Applicant respectfully submits that the acknowledgment that “apoptosis related protein which binds to NADE” includes some proteins which are currently unknown does not mean that the application fails to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants, therefore, respectfully request that the rejection of claims 3-5 and 7 be withdrawn.

***Response to §112, Second Paragraph Rejections***

Claims 3-5 and 7 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. The Office Action asserts that claims 3-5 and 7 are indefinite for omitting essential

elements, including a contacting step and a step correlating the detection step to the purpose in the preamble. In response, Applicants note that claim 3 has been amended to “adding a candidate medicament to be tested, NADE (p75NTR) and an apoptosis relating protein which binds to NADE to a system, and detecting and determining the effect on the binding.” Applicants again note that these steps, which are alleged to be missing, are all inherent in the claimed method, and are unnecessary. However, in the interest of lessening the outstanding issues to speed prosecution, Applicants have added these inherent steps. Therefore, Applicants respectfully submit that the rejection should be withdrawn.

Claims 4, 5 and 7 are rejected under 35 U.S.C. § 112, first second paragraph, as allegedly being indefinite. The Office Action asserts that claims 4, 5 and 7 are indefinite for use of the term “interaction”, or “interact.” In response, Applicants have amended the claims by deleting the terms “interaction” and replacing it with “binding”, and “interact” with “bind.” Therefore, Applicants respectfully submit that the basis for the rejection of claims 4, 5 and 7 is moot and should be withdrawn.

Therefore, Applicants respectfully submit that the rejection of claims 3-5 and 7 under 35 U.S.C. §112, second paragraph has been overcome, and should be withdrawn.

***Response to Objection under 37 C.F.R. 1.75(c)***

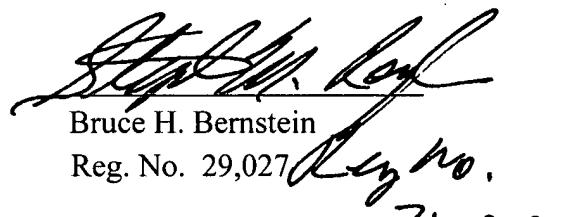
Claims 4, 5 and 7 are objected to under 37 C.F.R. 1.75(c) as allegedly being of improper dependent form. The Office Action asserts that claims 4, 5 and 7 are indefinite for use of the term “interaction”, or “interact.” Applicants note that the Office Action states that claim 6 is also objected to, but that this claim has been canceled by the previous Amendment.

As noted above, Applicants have amended the claims by deleting the term “interaction” and replacing it with “binding”, and “interact” with “bind.” Therefore, Applicants respectfully submit that the basis for the objection to claims 4, 5 and 7 is moot and should be withdrawn.

## CONCLUSION

For the reasons advanced above, Applicants respectfully submit that all pending claims patentably define Applicants' invention. Allowance of the application with an early mailing date of the Notices of Allowance and Allowability is therefore respectfully requested. If any issues remain which may be expeditiously resolved by a telephone conference, the Examiner is respectfully invited to telephone the undersigned at the below listed number to discuss the same.

Respectfully submitted,  
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